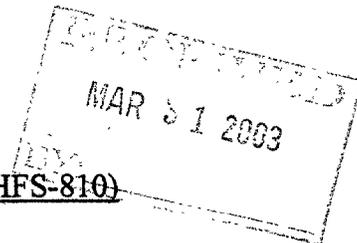




Whole Food Supplements

1986 '03 APR 15 P1:55

March 19, 2003



Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Ligaplex II provides support to tissues and joints involved in strenuous repetitive activity.
- (2) Ligaplex I and Ligaplex II contain vitamins, minerals, and Protomorphogen™ and Cytosol™ brand extracts to provide support to connective tissue and joints especially during times of increased demand.
- (3) The ingredients in each product work synergistically to bring essential nutrients to their cellular destinations and support chemical and physiological processes within tissues and joints.
- (4) The whole food ingredients found in Ligaplex I and Ligaplex II are formulated specifically to support healthy skeletal connective tissue by: providing organ tissue and tissue extracts that support connective tissue at the cellular level,
- (5) supplying vitamins and minerals that support connective tissue and joints in meeting the demands of everyday activity,
- (6) and supplying specific nutrients in a ratio that maximizes support and maintenance of connective tissue and joints during increased activity and repetitive movement

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- (7) The whole food ingredients in the Ligaplex supplements provide the following supportive benefits: antioxidant protection; the Ligaplex supplements contain vitamins A, C, and E – strong antioxidants that are recognized for providing cellular protection especially when combined synergistically,
- (8) Restorative properties; Ligaplex I and Ligaplex II contain bovine adrenal Cytosol™ brand extracts that promote the natural repair process at the cellular level of the joints.
- (9) Vitamins and minerals essential for connective tissue health; the vitamins in the Ligaplex supplements are required for tissue growth and repair.
- (10) Vitamin E promotes healthy circulation, enhances athletic performance, and helps ease muscle cramping.
- (11) Both Ligaplex supplements contain vitamin B12 important in cellular formation and longevity.
- (12) Calcium is required for strong bones and proper muscular growth and contraction – an important consideration during exercise.
- (13) Manganese is an important mineral for bone growth and the formation of cartilage and synovial fluid in joints.
- (14) Ligaplex II contains carbamide to stimulate proper tissue fluid metabolism and promote fluid balance in joints.
- (15) Bovine and ovine glandulars, plus veal bone Protomorphogen™ extract; specific organ tissues and extracts provide unique raw materials to like cells to help them restore, repair, and regenerate.
- (16) The patented process by which Protomorphogen™ brand extracts are extracted from animal tissues yields concentrated cellular components to promote healthy cellular function.



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- (17) The Ligaplex supplements, manufactured by Standard Process Inc., offer primary nutritional components, as well as synergistic cofactors, to provide natural nutritional support to the physiologic structures and biochemical processes of the entire skeletal system.
- (18) The benefits of many of the ingredients overlap in some areas, yet their combination with compounds from different whole food sources offers a unique blend of substances, providing optimal nutritional activity.

These statements are made for a dietary supplement containing nutritional yeast, carbamide, bovine bone, veal bone PMG™ extract, bovine liver, defatted wheat (germ), bovine heart PMG™ extract, magnesium citrate, oat flour, inositol, carrot (root), dried pea (vine) juice, *Tillandsia usneoides*, ribonucleic acid, beet (root), bovine spleen, ovine spleen, bovine adrenal Cytosol™ extract, bovine kidney, mushroom, bovine liver fat extract, flaxseed oil extract, potassium paraaminobenzoate, rice (bran) extract, and soy bean lecithin. Other ingredients include manganese glycerophosphate, gelatin, calcium lactate, water, calcium stearate, colors, mixed tocopherols, ascorbin acid, vitamin A palmitate, cellulose, cyanocobalamin and choliciferol. The name of the product is Ligaplex® II.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden
Standard Process Inc.